

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

MERCK EPROVA AG,

Plaintiff,

v.

BROOKSTONE PHARMACEUTICALS,  
LLC a/k/a ACELLA PHARMACEUTICALS,  
LLC,

Defendant.

No. 1:09-CV-9684(RJS)(JCF)

**DEFENDANT’S ANSWER AND AFFIRMATIVE DEFENSES TO THE FIRST  
AMENDED COMPLAINT, JURY DEMAND, AND COUNTERCLAIMS**

Defendant Brookstone Pharmaceuticals, LLC a/k/a Acella Pharmaceuticals, LLC (“Brookstone”), by and through counsel, states as follows, in like-numbered paragraphs, for its Answer to the First Amended Complaint (the “Complaint”):

**NATURE AND BASIS OF ACTION**

1. Brookstone admits that the Complaint seeks temporary, preliminary, and permanent injunctive relief, actual damages, punitive damages, and recovery of Plaintiff’s costs and reasonable attorneys’ fees incurred in connection with this action, but Brookstone denies Plaintiff is entitled to such relief or to any relief whatsoever. Brookstone denies the remaining allegations contained in paragraph 1 of the Complaint.

**PARTIES**

2. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 2 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 2 of the Complaint.

3. Brookstone admits that its principal place of business is at 9005 Westside Parkway, Alpharetta, Georgia. Brookstone denies the remaining allegations contained in paragraph 3 of the Complaint.

4. Brookstone admits that Brookstone Pharmaceuticals, LLC is in the process of changing its name to Acella Pharmaceuticals, LLC. Brookstone denies the remaining allegations contained in paragraph 4 of the Complaint.

### **JURISDICTION AND VENUE**

5. Brookstone denies the allegations contained in paragraph 5 of the Complaint.

6. Brookstone admits the allegations contained in paragraph 6 of the Complaint.

7. Brookstone admits that it transacts business in the State of New York, including the Southern District of New York. Brookstone denies the remaining allegations contained in paragraph 7 of the Complaint.

8. Brookstone admits that venue is proper in the Southern District of New York. Brookstone denies the remaining allegations contained in paragraph 8 of the Complaint.

### **FACTUAL BACKGROUND**

#### **A. Merck and Its L-5-MTHF Product: METAFOLIN®**

9. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 9 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 9 of the Complaint.

10. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 10 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 10 of the Complaint.

11. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 11 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 11 of the Complaint.

12. Brookstone admits the allegations contained in paragraph 12 of the Complaint.

13. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 13 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 13 of the Complaint.

14. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 14 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 14 of the Complaint.

15. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 15 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 15 of the Complaint.

16. On information and belief, Brookstone admits the allegations contained in paragraph 16 of the Complaint.

17. On information and belief, Brookstone admits the allegations contained in the first sentence of paragraph 17 of the Complaint. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in the second sentence of paragraph 17 of the Complaint and, accordingly, denies the allegations contained in the second sentence of paragraph 17 of the Complaint.

18. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 18 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 18 of the Complaint.

19. Brookstone denies the allegations contained in paragraph 19 of the Complaint.

20. On information and belief, Brookstone admits the allegations contained in paragraph 20 of the Complaint.

21. On information and belief, Brookstone admits the allegations contained in paragraph 21 of the Complaint.

22. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 22 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 22 of the Complaint.

23. Brookstone denies the allegations contained in paragraph 23 of the Complaint.

24. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 24 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 24 of the Complaint.

25. Brookstone denies that the L-5-MTHF used in Plaintiff's Metafolin® compound consists of a single diastereoisomer. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in paragraph 25 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 25 of the Complaint.

26. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 26 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 26 of the Complaint.

27. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 27 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 27 of the Complaint.

28. Brookstone admits that, in some naming conventions, diastereoisomers may be distinguished by identifying one diastereoisomer as the “D” isomer and identifying the other diastereoisomer as the “L” isomer. Brookstone denies the remaining allegations contained in paragraph 28 of the Complaint.

29. Brookstone admits that a racemic mixture of 5-methyltetrahydrofolate is a 1 to 1 mixture of two diastereoisomers, which may be referred to as the L and D isomers, respectively. Brookstone denies the remaining allegations contained in paragraph 29 of the Complaint.

30. Brookstone admits that the L isomer in L-methylfolate is biologically active and that the D isomer in L-methylfolate is a biologically inert impurity. Brookstone denies the remaining allegations contained in paragraph 30 of the Complaint.

31. Brookstone admits that the L isomer in L-methylfolate is the primary biologically active isomer of folate and the primary form of folate in circulation. Brookstone also admits that the L isomer in L-methylfolate is the form that is transported across membranes into peripheral tissues, particularly across the blood-brain barrier. Brookstone denies the remaining allegations contained in paragraph 31 of the Complaint.

32. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 32 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 32 of the Complaint.

33. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 33 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 33 of the Complaint.

34. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 34 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 34 of the Complaint.

35. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 35 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 35 of the Complaint.

36. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 36 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 36 of the Complaint.

37. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 37 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 37 of the Complaint.

38. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 38 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 38 of the Complaint.

39. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 39 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 39 of the Complaint.

40. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 40 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 40 of the Complaint.

41. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 41 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 41 of the Complaint.

**B. Generics**

42. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 42 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 42 of the Complaint.

43. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 43 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 43 of the Complaint.

44. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 44 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 44 of the Complaint.

45. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 45 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 45 of the Complaint.

46. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 46 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 46 of the Complaint.

47. Brookstone admits that pharmacy practice is governed by state and federal law. The remaining allegations contained in paragraph 47 of the Complaint assert legal conclusions to which Brookstone is not required to respond or otherwise concern matters about which

Brookstone lacks knowledge or information sufficient to form a belief about their truth. Accordingly, Brookstone denies the allegations contained in paragraph 47 of the Complaint.

48. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 48 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 48 of the Complaint.

**C. Defendant's Unlawful Conduct**

49. Brookstone admits the allegations contained in paragraph 49 of the Complaint.

50. Brookstone admits that it is a pharmaceutical company engaged in the development, marketing, and sale of a variety of products, some of which are generics. The remaining allegations contained in paragraph 50 of the Complaint are denied.

51. Brookstone denies the allegations as stated in paragraph 51 of the Complaint.

52. Brookstone denies the allegations contained in paragraph 52 of the Complaint.

53. Brookstone admits that prior to November 12, 2009, it contacted national pharmaceutical databases and supplied those databases with information about its PNV, PNV-DHA, and/or Folast products. The remaining allegations contained in paragraph 53 of the Complaint are denied.

54. Brookstone denies the allegations contained in paragraph 54 of the Complaint.

55. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 55 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 55 of the Complaint.

***Falsely Labeled Products: PNV-DHA PNV, and Folast***

56. Brookstone denies the allegations contained in paragraph 56 of the Complaint.



57. Brookstone admits that the allegations contained in paragraph 57 of the Complaint refer to a document that speaks for itself. Brookstone denies the remaining allegations contained in paragraph 57 of the Complaint.

58. Brookstone admits that its PNV-DHA product contains a methyltetrahydrofolate dietary ingredient, identified by Brookstone's Xolafin™ mark, that delivers, as an active isomer, L-methylfolate (L-5-MTHF). Brookstone denies the remaining allegations contained in paragraph 58 of the Complaint.

59. Brookstone admits that the allegations contained in paragraph 59 of the Complaint refer to a document that speaks for itself. Brookstone denies the remaining allegations contained in paragraph 59 of the Complaint.

60. Brookstone admits that its PNV product contains a methyltetrahydrofolate dietary ingredient, identified by Brookstone's Xolafin™ mark, that delivers, as an active isomer, L-methylfolate (L-5-MTHF). Brookstone denies the remaining allegations contained in paragraph 60 of the Complaint.

61. Brookstone admits that the allegations contained in paragraph 61 of the Complaint refer to a document that speaks for itself. Brookstone denies the remaining allegations contained in paragraph 61 of the Complaint.

62. Brookstone admits that its Folast product contains a methyltetrahydrofolate dietary ingredient, identified by Brookstone's Xolafin™ mark, that delivers, as an active isomer, L-methylfolate (L-5-MTHF). Brookstone denies the remaining allegations contained in paragraph 62 of the Complaint.

63. Brookstone admits that the allegations contained in paragraph 63 of the Complaint refer to documents that speak for themselves. In addition, Brookstone admits that its

PNV, PNV-DHA, and Folast products contain a methyltetrahydrofolate dietary ingredient, identified by Brookstone's Xolafin™ mark, that delivers, as an active isomer, L-methylfolate (L-5-MTHF). Brookstone denies the remaining allegations contained in paragraph 63 of the Complaint.

64. Brookstone admits that the allegations contained in paragraph 64 of the Complaint refer to a document that speaks for itself. Brookstone denies the remaining allegations contained in paragraph 64 of the Complaint.

65. Brookstone admits that the allegations contained in paragraph 65 of the Complaint refer to a document that speaks for itself. Brookstone denies the remaining allegations contained in paragraph 65 of the Complaint.

66. Brookstone admits that the allegations contained in paragraph 66 of the Complaint refer to a document that speaks for itself. Brookstone denies the remaining allegations contained in paragraph 66 of the Complaint.

67. Brookstone admits that its PNV, PNV-DHA, and Folast products contain a methyltetrahydrofolate dietary ingredient, identified by Brookstone's Xolafin™ mark, that delivers, as an active isomer, L-methylfolate (L-5-MTHF). Brookstone denies the remaining allegations contained in paragraph 67 of the Complaint.

68. Brookstone admits that the allegations contained in paragraph 68 of the Complaint refer to documents that speak for themselves. In addition, Brookstone admits that its PNV, PNV-DHA, and Folast products contain a methyltetrahydrofolate dietary ingredient, identified by Brookstone's Xolafin™ mark, that delivers, as an active isomer, L-methylfolate (L-5-MTHF). Brookstone denies the remaining allegations contained in paragraph 68 of the Complaint.

69. Brookstone denies the allegations contained in the first sentence of paragraph 69 of the Complaint. With regard to the second sentence of paragraph 69 of the Complaint, Brookstone admits that, as stated on the applicable package inserts and marketing materials, its PNV, PNV-DHA, and Folast products have not been subjected to FDA therapeutic equivalency or other equivalency testing. Brookstone expressly denies, however, that it has falsely represented its PNV, PNV-DHA, and Folast products. With regard to the third sentence of paragraph 69 of the Complaint, Brookstone denies that it has represented its PNV, PNV-DHA, and Folast products as generic versions of any other product. Brookstone denies the remaining allegations contained in paragraph 69 of the Complaint.

***Brookstone's False Advertising and Promotion***

70. Brookstone denies the allegations contained in paragraph 70 of the Complaint.

71. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 71 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 71 of the Complaint.

72. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 72 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 72 of the Complaint.

73. Brookstone denies the allegations contained in paragraph 73 of the Complaint.

74. Brookstone admits that the allegations contained in paragraph 74 of the Complaint refer to documents that speak for themselves. In addition, Brookstone admits that its PNV, PNV-DHA, and Folast products contain a methyltetrahydrofolate dietary ingredient, identified by Brookstone's Xolafin™ mark, that delivers, as an active isomer, L-methylfolate (L-

5-MTHF). Brookstone denies the remaining allegations contained in paragraph 74 of the Complaint.

75. Brookstone denies the allegations contained in paragraph 75 of the Complaint.

76. Brookstone admits that the allegations contained in paragraph 76 of the Complaint refer to documents that speak for themselves and that, as stated on the applicable package inserts and marketing materials, its PNV, PNV-DHA, and Folast products have not been subjected to FDA therapeutic equivalency or other equivalency testing. Brookstone expressly denies, however, that it has falsely represented its PNV, PNV-DHA, and Folast products. Brookstone denies the remaining allegations contained in paragraph 76 of the Complaint.

77. Brookstone admits that the allegations contained in paragraph 76 of the Complaint refer to a document that speaks for itself. Brookstone denies the remaining allegations contained in paragraph 77 of the Complaint.

78. Brookstone admits that the allegations contained in paragraph 78 of the Complaint refer to documents that speak for themselves. In addition, Brookstone admits that its PNV, PNV-DHA, and Folast products contain a methyltetrahydrofolate dietary ingredient, identified by Brookstone's Xolafin™ mark, that delivers, as an active isomer, L-methylfolate (L-5-MTHF). Brookstone denies the remaining allegations contained in paragraph 74 of the Complaint.

79. Brookstone admits that its PNV, PNV-DHA, and Folast products contain a methyltetrahydrofolate dietary ingredient, identified by Brookstone's Xolafin™ mark, that delivers, as an active isomer, L-methylfolate (L-5-MTHF). Brookstone lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations contained in

paragraph 79 of the Complaint. Accordingly, Brookstone denies the remaining allegations contained in paragraph 79 of the Complaint.

80. Brookstone lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 80 of the Complaint. Accordingly, Brookstone denies the allegations contained in paragraph 80 of the Complaint.

81. Brookstone denies the allegations contained in paragraph 81 of the Complaint.

82. Brookstone denies the allegations contained in paragraph 82 of the Complaint.

83. Brookstone denies the allegations contained in paragraph 83 of the Complaint.

### **COUNT I**

#### **FALSE ADVERTISING IN VIOLATION OF SECTION 43(a)(1)(B) OF THE LANHAM ACT, 15 U.S.C. § 1125(a)(1)(B)**

84. Paragraph 84 of the Complaint contains no allegations to which Brookstone is required to respond. Brookstone incorporates by reference its responses to paragraphs 1 through 83 of the Complaint as though fully set forth herein. To the extent a further response is deemed required, Brookstone denies the allegations contained in paragraph 84 of the Complaint.

85. Brookstone denies the allegations contained in paragraph 85 of the Complaint.

86. Brookstone denies the allegations contained in paragraph 86 of the Complaint.

87. Brookstone denies the allegations contained in paragraph 87 of the Complaint.

88. Brookstone denies the allegations contained in paragraph 88 of the Complaint.

89. Brookstone denies the allegations contained in paragraph 89 of the Complaint.

90. Brookstone denies the allegations contained in paragraph 90 of the Complaint.

**COUNT II**

**CONTRIBUTORY FALSE ADVERTISING IN VIOLATION OF SECTION 43(a)(1)(B) OF THE LANHAM ACT, 15 U.S.C. § 1125(a)(1)(B)**

91. Paragraph 91 of the Complaint contains no allegations to which Brookstone is required to respond. Brookstone incorporates by reference its responses to paragraphs 1 through 90 of the Complaint as though fully set forth herein. To the extent a further response is deemed required, Brookstone denies the allegations contained in paragraph 91 of the Complaint.

92. Brookstone denies the allegations contained in paragraph 92 of the Complaint.

93. Brookstone denies the allegations contained in paragraph 93 of the Complaint.

94. Brookstone denies the allegations contained in paragraph 94 of the Complaint.

95. Brookstone denies the allegations contained in paragraph 95 of the Complaint.

96. Brookstone denies the allegations contained in paragraph 96 of the Complaint.

97. Brookstone denies the allegations contained in paragraph 97 of the Complaint.

98. Brookstone denies the allegations contained in paragraph 98 of the Complaint.

**COUNT III**

**FEDERAL UNFAIR COMPETITION IN VIOLATION OF SECTION 43(a)(1)(A) OF THE LANHAM ACT, 15 U.S.C. § 1125(a)(1)(A)**

99. Paragraph 99 of the Complaint contains no allegations to which Brookstone is required to respond. Brookstone incorporates by reference its responses to paragraphs 1 through 98 of the Complaint as though fully set forth herein. To the extent a further response is deemed required, Brookstone denies the allegations contained in paragraph 99 of the Complaint.

100. Brookstone denies the allegations contained in paragraph 100 of the Complaint.

101. Brookstone denies the allegations contained in paragraph 101 of the Complaint.

102. Brookstone denies the allegations contained in paragraph 102 of the Complaint.

103. Brookstone denies the allegations contained in paragraph 103 of the Complaint.

104. Brookstone denies the allegations contained in paragraph 104 of the Complaint.

105. Brookstone denies the allegations contained in paragraph 105 of the Complaint.

106. Brookstone denies the allegations contained in paragraph 106 of the Complaint.

#### **COUNT IV**

##### **COMMON LAW UNFAIR COMPETITION**

107. Paragraph 107 of the Complaint contains no allegations to which Brookstone is required to respond. Brookstone incorporates by reference its responses to paragraphs 1 through 106 of the Complaint as though fully set forth herein. To the extent a further response is deemed required, Brookstone denies the allegations contained in paragraph 107 of the Complaint.

108. Brookstone denies the allegations contained in paragraph 108 of the Complaint.

109. Brookstone denies the allegations contained in paragraph 109 of the Complaint.

110. Brookstone denies the allegations contained in paragraph 110 of the Complaint.

111. Brookstone denies the allegations contained in paragraph 111 of the Complaint.

112. Brookstone denies the allegations contained in paragraph 112 of the Complaint.

113. Brookstone denies the allegations contained in paragraph 113 of the Complaint.

#### **COUNT V**

##### **DECEPTIVE TRADE PRACTICES IN VIOLATION OF N.Y. GEN. BUS. LAW § 349(h)**

114. Paragraph 114 of the Complaint contains no allegations to which Brookstone is required to respond. Brookstone incorporates by reference its responses to paragraphs 1 through 113 of the Complaint as though fully set forth herein. To the extent a further response is deemed required, Brookstone denies the allegations contained in paragraph 114 of the Complaint.

115. Brookstone denies the allegations contained in paragraph 115 of the Complaint.

116. Brookstone denies the allegations contained in paragraph 116 of the Complaint.

117. Brookstone denies the allegations contained in paragraph 117 of the Complaint.

118. Brookstone denies the allegations contained in paragraph 118 of the Complaint.

119. Brookstone denies the allegations contained in paragraph 119 of the Complaint.

## **COUNT VI**

### **FALSE ADVERTISING IN VIOLATION OF N.Y. GEN. BUS. LAW § 350(e)(3)**

120. Paragraph 120 of the Complaint contains no allegations to which Brookstone is required to respond. Brookstone incorporates by reference its responses to paragraphs 1 through 119 of the Complaint as though fully set forth herein. To the extent a further response is deemed required, Brookstone denies the allegations contained in paragraph 120 of the Complaint.

121. Brookstone denies the allegations contained in paragraph 121 of the Complaint.

122. Brookstone denies the allegations contained in paragraph 122 of the Complaint.

123. Brookstone denies the allegations contained in paragraph 123 of the Complaint.

124. Brookstone denies the allegations contained in paragraph 124 of the Complaint.

125. Brookstone denies the allegations contained in paragraph 125 of the Complaint.

## **PRAYER FOR RELIEF**

Brookstone specifically denies Plaintiff's entitlement to the relief set forth in Plaintiff's unnumbered paragraph under the heading "Prayer for Relief."

Any allegation contained in the Complaint which is not expressly admitted or denied above is hereby denied.

## **DEFENDANT'S AFFIRMATIVE DEFENSES**

For its Affirmative Defenses against to the claims asserted by Plaintiff, Defendant Brookstone states as follows:

### **FIRST AFFIRMATIVE DEFENSE**

Plaintiff's Complaint fails to state a claim upon which relief can be granted.



### **SECOND AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred by the doctrines of preclusion and preemption.

### **THIRD AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred, because Brookstone's advertising is not false or misleading, has not actually deceived and does not have the capacity to deceive customers, does not constitute deception that has a material effect on purchasing decisions, and has not injured and is not likely to injure Plaintiff.

### **FOURTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred, because they are not based on advertising as recognized under the Lanham Act.

### **FIFTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred, because Plaintiff and Brookstone are not competitors.

### **SIXTH AFFIRMATIVE DEFENSE**

Plaintiff's contributory false advertising claim is not legally cognizable and is therefore barred.

### **SEVENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred or limited by the doctrines of unclean hands and other principles of equity.

### **EIGHTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred by the doctrines of waiver and estoppel.

### **NINTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred by the doctrine of laches.

**TENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred or limited, because any damages sustained by Plaintiff were not the proximate result of any actionable conduct on the part of Brookstone, nor were any such damages caused in fact by any actionable conduct on the part of Brookstone.

**ELEVENTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred, because of the lack of subject matter jurisdiction.

**TWELFTH AFFIRMATIVE DEFENSE**

Plaintiff's claims are barred, because Plaintiff lacks standing.

**THIRTEENTH AFFIRMATIVE DEFENSE**

Plaintiff is not entitled to injunctive relief, because the damages alleged by Plaintiff are not irreparable, the harm to Brookstone resulting from injunctive relief would be greater than any harm sustained by Plaintiff in the absence of an injunction, and the public interest would not be served by injunctive relief in this action.

**FOURTEENTH AFFIRMATIVE DEFENSE**

Brookstone reserves the right to amend this answer and to add additional defenses and counterclaims as its investigation and discovery in this action progress.

**JURY DEMAND**

Brookstone demands trial by jury on all issues in this action.

**DEFENDANT'S COUNTERCLAIMS**

For its Counterclaims against Plaintiff/Counter-Defendant Merck, Defendant/Counterclaimant Brookstone states as follows:

### COUNTERCLAIM FOR DECLARATORY JUDGMENT

1. Merck alleges, in its Complaint filed in this action, that Brookstone falsely labels its products, PNV Select, PNV-DHA, and Folast (“the Brookstone Products”) as containing or using genuine or pure L-methylfolate and that Brookstone had engaged in contributory false advertising by inducing or encouraging national pharmaceutical databases to falsely advertise the Brookstone Products as pharmaceutically equivalent to or substitutable products containing Merck’s Metafolin® compound.

2. Merck’s First Amended Complaint creates ripe and justiciable issues for the Court to adjudicate.

3. As set forth in its Answer, Brookstone denies that it has or is engaged in any wrongful conduct.

4. The plain, ordinary meaning of “genuine” is “real,” for example as defined by Merriam-Webster’s Collegiate Dictionary:

1 a: actually having the reputed or apparent qualities or character;  
b: *actually produced by or proceeding from the alleged source* or author; c: sincerely or honestly felt or experienced; d: actual, true; 2: free from hypocrisy or pretense.

Merriam-Webster’s Collegiate Dictionary 486 (10th ed. 1999) (emphasis added).

5. L-methylfolate and its synonym, L-5-MTHF, are terms that Merck uses to identify a particular chemical compound that can deliver folate to the human body, L-5-methyltetrahydrofolic acid.

6. The term “L-methylfolate,” when used to indicate the presence of genuine or real L-5-methyltetrahydrofolic acid in a composition, does not indicate whether the chemical compound is present with or without the diastereoisomer D-5-methyltetrahydrofolic acid, which can be identified as D-methylfolate or D-5-MTHF.

7. The term “L-methylfolate,” when used to indicate the presence of genuine or real L-5-methyltetrahydrofolic acid in a composition, does not indicate the level of purity of such chemical compound in that composition.

8. The Brookstone Products contain genuine, i.e., real, L-methylfolate.

9. The genuine L-methylfolate in the Brookstone Products is present as part of a non-racemic mixture that also consists of genuine, i.e., real, D-methylfolate. On information and belief, the genuine L-methylfolate in Metafolin® is also present as a part of a non-racemic mixture that also contains genuine, i.e., real, D-methylfolate.

10. The mixture of L- and D-methylfolate used in the Brookstone Products is identified as Xolafin™.

11. The Xolafin™ identified in and complained of in Merck’s First Amended Complaint consists of genuine L-methylfolate (as well as genuine D-methylfolate).

12. Merck does not dispute that the Brookstone Products containing Xolafin™ contain genuine L-methylfolate.

13. The labeling and other documents published by Brookstone accurately and truthfully identify genuine L-methylfolate as a component of the Brookstone Products by its generic, scientifically accurate name.

14. The labeling and other documents published by Brookstone accurately and truthfully identify the genuine L-methylfolate in the Brookstone Products as being genuine L-methylfolate.

15. On information and belief, Merck filed its First Amended Complaint with knowledge that Brookstone’s labeling and other documentation relating to the Brookstone

Products accurately and truthfully identify genuine L-methylfolate as a component of the Brookstone Products by its generic, scientifically accurate name.

16. On information and belief, Merck filed its First Amended Complaint with knowledge that Brookstone's labeling and other documentation relating to the Brookstone Products accurately and truthfully identify the genuine L-methylfolate in the Brookstone Products as being genuine L-methylfolate.

17. Brookstone has never described the genuine L-methylfolate in Xolafin™ as "pure" or "substantially pure" L-methylfolate and has never described Xolafin®™ as "pure" (i.e., consisting only of) L-methylfolate.

18. Brookstone has never used the word "pure" or the phrase "substantially pure" to describe Xolafin™ or the genuine L-methylfolate in the Brookstone Products.

19. On information and belief, Merck has no evidence of Brookstone describing the genuine L-methylfolate in Xolafin™ or in the Brookstone Products as "pure" or "substantially pure" L-methylfolate.

20. On information and belief, Merck has no evidence of Brookstone using the word "pure" or the phrase "substantially pure" to describe the genuine L-methylfolate in Xolafin™ or in the Brookstone Products.

21. On information and belief, the national pharmaceutical databases have never described the genuine L-methylfolate in Xolafin™ or the genuine L-methylfolate in Metafolin® or products containing Metafolin® as "pure" or "substantially pure" L-methylfolate, and have never described Xolafin®™ or Metafolin® as "pure" (i.e., consisting only of) L-methylfolate.

22. On information and belief, the national pharmaceutical databases have never used the word “pure” or the phrase “substantially pure” to describe Xolafin™ or the genuine L-methylfolate in either the Brookstone Products or Metafolin®.

23. Brookstone has no ultimate control over the business or professional practices of the national pharmaceutical databases or of pharmacists.

24. Brookstone has never encouraged, asked, or otherwise induced the national pharmaceutical databases – or any other person or entity – to label or otherwise describe the Brookstone Products or Xolafin™ as “pure” or “substantially pure” L-methylfolate.

25. Brookstone has never encouraged, asked, or otherwise induced the national pharmaceutical databases – or any other person or entity – to improperly use Merck’s name or marks or Merck’s customers’ names or marks.

#### **COUNTERCLAIM FOR FALSE ADVERTISING UNDER THE LANHAM ACT**

26. Brookstone hereby incorporates the allegations contained in paragraphs 1 through 25 of this counterclaim as though fully set forth herein. In the event, and to the extent, that Merck is found to have standing to pursue Lanham Act claims against Brookstone that are not precluded, Brookstone asserts the following counterclaim.

27. Merck manufactures a chemical compound consisting of L-methylfolate and D-methylfolate for use in dietary supplement. Merck markets and sells and/or licenses this compound in interstate commerce under the Metafolin® mark, which is owned by Merck KGaA and licensed to Merck.

28. Merck devotes significant financial resources each year to marketing Metafolin®, which, Merck claims, is a product that is critical to enhance the health of a consumer population with specific nutritional needs.

29. Merck markets Metafolin® to customers, including Sciele Pharma, Inc. (“Sciele”) and PamLab, LLC (“PamLab”), as providing the customers’ products with a distinctive selling point, because Metafolin® contains L-methylfolate.

30. Sciele and PamLab purchase and/or license Metafolin® from Merck for use in their respective products which compete with products developed, marketed, and sold by Brookstone. Sciele and PamLab, in turn, advertise and market their products by promoting the fact that their products contain Metafolin®.

31. Merck also promotes and advertises Metafolin® directly to consumers, and others, via the Internet through a publicly-available website owned and maintained by Merck, [www.metafolin.com](http://www.metafolin.com).

32. Merck’s marketing of Metafolin® focuses on Merck’s assertion that L-methylfolate is the naturally occurring form of folate in food and the human body.

33. Merck’s marketing efforts promote Metafolin® as a unique ingredient and seek to differentiate it from other sources of folate for use in dietary supplements.

34. Merck receives substantial revenue – on information and belief, millions of dollars – from selling and/or licensing Metafolin® to its customers.

35. Unlike drugs, neither Metafolin® nor dietary supplements containing Metafolin® are products which are subject to approval by the U.S. Food and Drug Administration (“FDA”), although these products are regulated by the FDA.

36. Merck filed a New Dietary Ingredient Notification (“NDI”) with the FDA in 2001 for the chemical compound which is marketed and sold and/or licensed as Metafolin®.

37. As part of its marketing efforts, Merck promotes Metafolin® on its website, [www.metafolin.com](http://www.metafolin.com), by touting its NDI. As of January 28, 2010, [www.metafolin.com](http://www.metafolin.com) contained the following entry in a timeline advertising the regulatory status of Metafolin®:

**2001 U.S. FDA: New Dietary Ingredient Notification for Metafolin®**  
U.S. FDA accepts L-methylfolate as a source of the naturally-occurring form of folate.

(Metafolin – Regulatory Status, available at [www.metafolin.com/servlet/PB/menu/1784940/index.html](http://www.metafolin.com/servlet/PB/menu/1784940/index.html) (last accessed on Jan. 28, 2010), Ex. 1 to Counterclaim, at 1.)

38. The same advertisement also represents that “Metafolin® is also known as L-methylfolate....” (Ex. 1 at 1.)

39. An NDI is submitted to the FDA when a person or entity wishes to sell a product containing an ingredient which was not marketed in the United States before October 15, 1994. Food, Drug, and Cosmetic Act, 21 U.S.C. § 350b(c).

40. The purpose of an NDI is not to legally define or approve dietary ingredients or products or to make, accept, or approve statements, for use in advertisement or otherwise, about the nature or characteristics of an ingredient or product.

41. Rather, an NDI is intended to make the FDA aware that a person or entity has decided to include what it considers to be a new ingredient in a product going to market. The person or entity submitting the notification, not the FDA, identifies the ingredient it intends to use and its properties.

42. In connection with the submission of an NDI, the FDA makes no statement or ruling – whether express or implied – about an ingredient or product, including whether it is, in fact, a “new” ingredient. In fact, the FDA reserves the right to determine subsequently whether the allegedly new ingredient is unsafe or adulterated.



43. On information and belief, through at least its advertisement of Metafolin® on its website, [www.metafolin.com](http://www.metafolin.com), Merck promotes and represents Metafolin® to consumers, physicians, pharmacists, and its customers as approved, accepted, or validated by the FDA and/or that the FDA has approved, recognized, accepted, or validated that Metafolin® or the L-methylfolate component of Metafolin® is “a source of the naturally-occurring form of folate.”

44. Metafolin® is not approved by the FDA and, by virtue of Merck’s NDI or otherwise, the FDA has not approved, recognized, accepted, or validated that Metafolin® or the L-methylfolate component of Metafolin® is “a source of the naturally-occurring form of folate.”

45. Accordingly, Merck has falsely advertised, and continues to falsely advertise, Metafolin® by representing and promoting its product as approved by the FDA and by representing that the FDA has recognized, accepted, or validated alleged product characteristics which Merck uses to promote Metafolin®.

46. On information and belief, Merck has knowledge that Metafolin® is not FDA-approved and that the FDA has not recognized, accepted, or validated that Metafolin® or the L-methylfolate component of Metafolin® is “a source of the naturally-occurring form of folate.”

47. Merck’s advertising and promotion materially misrepresent the nature, characteristics, and qualities of Metafolin® and are intended to induce and, in fact, cause consumers, physicians, pharmacists, Merck’s customers, and others in the healthcare community to rely on the representations made by Merck in making purchasing, prescribing, and dispensing decisions.

48. Merck’s false advertising and promotion of Metafolin® have caused, and will continue to cause, damage to Brookstone in an amount to be determined at trial.

**WHEREFORE**, Brookstone respectfully requests that this Court:

(a) Enter judgment in favor of Brookstone and against Plaintiff and dismiss Plaintiff's Complaint with prejudice;

(b) Enter judgment declaring that Brookstone's accurate and truthful identification of the genuine L-methylfolate in the Brookstone Products and Xolafin™ is not wrongful conduct constituting a basis for a cause of action under federal or state law;

(c) Enter judgment declaring that Brookstone's accurate and truthful description of the Brookstone Products and Xolafin™ as containing L-methylfolate, where the Brookstone Products and Xolafin™ also contain D-methylfolate, is not wrongful conduct constituting a basis for a cause of action under federal or state law;

(d) Enter judgment declaring that Brookstone's accurate and truthful identification of L-methylfolate as a component of the Brookstone Products or Xolafin™ is not wrongful and does not constitute a basis for a cause of action under federal or state law;

(e) Impanel a jury to hear and decide all triable issues in this action;

(f) Enter judgment that Merck, as a result of its willful, deliberate, and materially false statements and advertisements regarding the quality, content, and nature of its product, has engaged in false advertising in violation of the Lanham Act;

(g) Award Brookstone compensatory damages caused by Merck's violation of the Lanham Act and punitive damages in an amount sufficient to punish Merck and deter it from engaging in further violations of the Lanham Act;

(h) Enter judgment finding that this is an exceptional case and awarding Brookstone treble damages;

(i) Tax the costs of this action against Plaintiff;

(j) Award Brookstone its attorneys' fees as the prevailing party under the Lanham Act; and

(k) Grant Brookstone such other and further relief to which it is entitled at law or in equity.

Dated this 29th day of January, 2010.

Respectfully submitted,

**HARRIS BEACH PLLC**

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